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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/069,541      | 02/27/2002  | Tatsuya Haga         | 31671-176438        | 1435             |

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/22/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/069,541

Applicant(s)

HAGA ET AL.

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-98 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 3, 4, 14, 15, 16, 23, 24, 34, and 35 (each in part), drawn to a gene comprising SEQ ID NO: 1, a protein comprising an amino acid sequence represented by SEQ ID NO: 2, fusion proteins, and a host cell expression system comprising the same.

Group II, claim(s) 1, 5, 6, 7, 14, 17, 18, 23, 25, 34, and 36 (each in part), drawn to a gene comprising SEQ ID NO: 3, a protein comprising an amino acid sequence represented by SEQ ID NO: 4, fusion proteins, and a host cell expression system comprising the same.

Group III, claim(s) 1, 8, 9, 10, 14, 19, 20, 26, 34, 37, 64, 65, and 67 (each in part), drawn to a gene comprising SEQ ID NO: 5, a protein comprising an amino acid sequence represented by SEQ ID NO: 6, fusion proteins, a host cell expression system, and host cell comprising the same.

Group IV, claim(s) 1, 11, 12, 13, 14, 21, 22, 23, 27, 34, and 38 (each in part), drawn to a gene comprising SEQ ID NO: 7, a protein comprising an amino acid sequence represented by SEQ ID NO: 8, fusion proteins, and a host cell expression system comprising the same.

Group V, claim(s) 28, 29, and 33 (each in part) drawn to an antibody which specifically binds to a protein comprising SEQ ID NO: 2.

Group VI, claim(s) 28, 30, and 33 (each in part) drawn to an antibody which specifically binds to a protein comprising SEQ ID NO: 4.

Group VII, claim(s) 28, 31, and 33 (each in part) drawn to an antibody which specifically binds to a protein comprising SEQ ID NO: 6.

Group VIII, claim(s) 28, 32, and 33 (each in part) drawn to an antibody which specifically binds to a protein comprising SEQ ID NO: 8.

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Group IX, claim(s) 39, 40, and 44 (each in part), drawn to a non-human animal who is deficient in or overexpresses a protein having high-affinity choline transport activity comprising SEQ ID NO: 2.

Group X, claim(s) 39, 41, and 44 (each in part), drawn to a non-human animal who is deficient in or overexpresses a protein having high-affinity choline transport activity comprising SEQ ID NO: 4.

Group XI, claim(s) 39, 42, and 44 (each in part), drawn to a non-human animal who is deficient in or overexpresses a protein having high-affinity choline transport activity comprising SEQ ID NO: 6.

Group XII, claim(s) 39, 43, and 44 (each in part), drawn to a non-human animal who is deficient in or overexpresses a protein having high-affinity choline transport activity comprising SEQ ID NO: 8.

Group XIII, claim(s) 45, 46, and 66 drawn to a preparing method of a cell and cells made thereby.

Group XIV, claim(s) 47, drawn to a cell having high-affinity choline transporter activity.

Group XV, claim(s) 48-51 and 68-70, drawn to a screening method of a promoter or a suppressor of high-affinity choline transport activity.

Group XVI, claim(s) 52 and 56, drawn to a screening method of a promoter or a suppressor of high-affinity choline transport activity using a cell obtained from a transgenic non-human animal.

Group XVII, claim(s) 53-55 and 71-73, drawn to a screening method of a promoter or a suppressor of high-affinity choline transport activity using a transgenic non-human animal.

Group XVIII, claim(s) 57 and 74-78, drawn to a material which promotes activity or expression of a protein having high-affinity choline transporter activity.

Group XIX, claim(s) 58 and 79-83, drawn to a material which suppresses activity or expression of a protein having high-affinity choline transporter activity.

Group XX, claim(s) 59 and 84-89, drawn to a medical constituent characterized in being used for medical treatment of a patient who needs elevation of the activity or expression of a high-affinity choline transporter.

Group XXI, claim(s) 60 and 90-95, drawn to a medical constituent characterized in being used for medical treatment of a patient who needs suppression of the activity or expression of a high-affinity choline transporter.

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Group XXII, claim(s) 61 and 96, drawn to a diagnostic method for diseases relating to the expression or the activity of a high-affinity choline transporter.

Group XXIII, claim(s) 62-63 and 97-98, drawn to a diagnostic probe for Alzheimer's disease comprising a whole or part of an antisense strand of DNA or RNA.

4. The inventions listed as Groups I-XXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

5. This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. Claim 1 is anticipated by prior art. Nikawa et al. [Primary Structure of the Yeast Choline Transport Gene and Regulation of Its Expression. (15 September 1990) Journal of Biological Chemistry 265(26): 15996-16003] teaches the isolation and characterization of a choline transport gene (CTR) from the yeast *Saccharomyces cerevisiae* (FIG 1-4). The instant application (10/069541) discloses that the invention is a gene encoding a protein having high-affinity choline transporter activity. Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN

January 2<sup>nd</sup>, 2003

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER